



## Complete Summary

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### GUIDELINE TITLE

ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to update the 2001 guidelines for percutaneous coronary intervention).

### BIBLIOGRAPHIC SOURCE(S)

Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Assoc Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to update the 2001 guidelines for PCI). Bethesda (MD): American College of Cardiology Foundation (ACCF); 2005. 122 p. [926 references]

### GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Smith SC, Dove JT, Jacobs AK, et al. ACC/AHA guidelines for percutaneous coronary intervention (revision of the 1993 PTCA guidelines). J Am Coll Cardiol 2001 Jun; 37(8): 2239i-lxvi.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Coronary artery disease, including:

- Asymptomatic ischemia or Canadian Cardiovascular Society (CCS) class I or II angina
- CCS class III angina
- Unstable angina/non-ST-elevation myocardial infarction (NSTEMI)
- ST-elevation myocardial infarction (STEMI)
- Ischemia (early or late) after coronary artery bypass graft

## GUIDELINE CATEGORY

Evaluation  
Management  
Treatment

## CLINICAL SPECIALTY

Cardiology  
Family Practice  
Geriatrics  
Internal Medicine  
Surgery

## INTENDED USERS

Physicians

## GUIDELINE OBJECTIVE(S)

To make recommendations regarding the appropriate use of percutaneous coronary interventions in the treatment of patients with coronary artery disease

## TARGET POPULATION

Patients with coronary artery disease

## INTERVENTIONS AND PRACTICES CONSIDERED

Management/Treatment

1. Percutaneous coronary interventions (PCI), including percutaneous transluminal coronary angioplasty (PTCA), balloon expandable stents, drug-eluting stents, extraction atherectomy, directional coronary atherectomy, rotational atherectomy, rheolytic thrombectomy catheter, proximal and distal embolic protection devices, excimer laser coronary atherectomy, and local radiation devices to reduce in-stent restenosis
2. Insurance of institutional and operator competency in performing (PCI) (quality assurance programs, high-volume operators in high-volume institutions, availability of onsite cardiac surgical back-up or access to cardiac surgical back-up)
3. Antiplatelet and antithrombotic adjunctive therapies (aspirin, clopidogrel, glycoprotein IIb/IIIa Inhibitors, unfractionated heparin, low-molecular-weight heparin, bivalirudin) in patients undergoing PCI

4. Special considerations (for example, management of clinical restenosis, ad hoc PCI, PCI in the cardiac transplant patient, and restenosis after stent implantation)
5. Post-PCI management (postprocedural evaluation of ischemia, risk factor modification, exercise testing, follow-up coronary angiography)

#### Evaluation/Follow-up

1. Angiographic assessment
2. Use of adjunctive technologies
  - Coronary intravascular ultrasound imaging (IVUS)
  - Measurement of coronary flow velocity and coronary vasodilatory reserve
  - Measurement of coronary artery pressure and fractional flow reserve (FFR)
3. Measurement of creatine kinase-MB isoenzyme and troponins I or T

#### MAJOR OUTCOMES CONSIDERED

- Success rates of percutaneous coronary intervention procedures as defined by angiographic (minimum stenosis diameter reduction to <20%), procedural, and clinical criteria (relief of signs and symptoms, rate of restenosis)
- Rates of procedural complications of percutaneous coronary intervention, such as: death, myocardial infarction, emergency coronary artery bypass graft (CABG), stroke, vascular access site complications, and contrast agent nephropathy
- Long-term (5- and 10-year) survival rates and event-free survival rates

### METHODOLOGY

#### METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)  
 Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The committee conducted comprehensive searching of the scientific and medical literature on percutaneous coronary intervention (PCI), with special emphasis on randomized controlled trials and meta-analyses published since 2001. In addition to broad-based searching on PCI, specific targeted searches were performed on the following subtopics: catheter-based intervention, stents (drug-eluting and bare-metal), cardiac biomarkers (e.g., creatine kinase and troponins), pharmacological therapy (aspirin, thienopyridines, GP IIb/IIIa inhibitors, heparin, and direct thrombin inhibitors), special populations (women, patients with diabetes, elderly), coronary artery bypass grafting (CABG), high-risk PCI, quality, outcomes, volume, left main PCI (protected and unprotected), distal embolic protection, intravascular ultrasound (IVUS), fractional flow reserve (FFR), vascular closure, and secondary prevention/risk factor modification. The complete list of keywords is beyond the scope of this section. The committee reviewed all compiled reports from computerized searches and conducted additional searching

by hand. Literature citations were generally restricted to published manuscripts appearing in journals listed in Index Medicus. Because of the scope and importance of certain ongoing clinical trials and other emerging information, published abstracts were cited when they were the only published information available. Additionally, the Committee reviewed and incorporated recommendations and/or text from published American College of Cardiology/American Heart Association (ACC/AHA) or Society for Cardiovascular Angiography and Interventions (SCAI) documents to maintain consistency, as appropriate.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

#### METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence

Level A: Data derived from multiple randomized clinical trials or meta-analyses.

Level B: Data derived from a single randomized trial or nonrandomized studies.

Level C: Only consensus opinion of experts, case studies, or standard-of-care.

#### METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Writing groups were specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might influence the choice of particular tests or therapies are considered, along with frequency of follow-up and cost-effectiveness.

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

#### DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Experts in the subject under consideration are selected from the American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Interventions (SCAI) to examine subject-specific data and write guidelines. The process includes additional representatives from other medical specialty groups where appropriate. Writing groups are specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might influence the choice of particular tests or therapies are considered as well as frequency of follow-up and cost-effectiveness.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment

Class IIa: Weight of evidence/opinion is in favor of usefulness/efficacy.

Class IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful

#### COST ANALYSIS

Among all diseases worldwide, ischemic heart disease currently ranks fifth in disability burden, and is projected to rank first by the year 2020. As healthcare delivery systems in countries with established economic markets continue to incorporate new and expensive technologies, the costs of medical care have seemingly escalated beyond the revenue historically allotted to health care. Given limited healthcare resources, a cost-effectiveness analysis is appropriate to evaluate percutaneous coronary revascularization strategies. The results of cost-effectiveness analyses for any comparable treatment are reported in terms of the incremental cost per unit of health gained, such as 1 year of life adjusted to perfect health (quality-adjusted life year, QALY) compared with the standard of care. By modeling different treatments, different patient subsets, and different levels of disease, a series of cost-effectiveness ratios may be constructed to show the tradeoffs associated with choosing among competing interventions.

Although there is no established cost-effectiveness ratio threshold, cost-effectiveness ratios of less than \$20,000 per QALY (such as seen in the treatment of severe diastolic hypertension or cholesterol lowering in patients with ischemic heart disease) are considered highly favorable and consistent with well accepted therapies. Incremental cost-effectiveness ratios that range between \$20,000 and \$60,000 per QALY may be viewed as reasonably cost-effective and thus acceptable in most countries, whereas ratios greater than \$60,000 to \$80,000 may be considered too expensive for most healthcare systems. The Committee defines useful and efficacious treatments, in terms of cost-effectiveness, as

treatments with acceptable or favorable cost-effectiveness ratios. Cost-effectiveness analysis is not by itself sufficient to incorporate all factors necessary for medical decision making on an individual patient basis, nor is it sufficient to dictate the broad allocation of societal resources for health care. Rather, cost-effectiveness analysis aims to serve mainly as an aid to medical decision making on the basis of comparison with other evaluated therapies.

The results of cost-effectiveness analysis in the field of percutaneous revascularization for ischemic heart disease have been derived from decision models that incorporate literature-based procedure-related morbidity and mortality, coronary disease related mortality, and estimates of the benefit of selected revascularization procedures. When available, results from randomized trials (levels of evidence A and B) are used to estimate the outcomes of each decision tree branch within the decision-analytical model, for example, using data estimating the restenosis rate after uncomplicated coronary stenting of a single, simple, lesion. Cost-effectiveness analyses have been used to compare medical therapy with percutaneous transluminal coronary angioplasty (PTCA) with coronary artery bypass graft (CABG), balloon angioplasty with coronary stenting, and routine coronary angiography following acute myocardial infarction (MI) with symptom-driven coronary angiography.

In patients with severe angina, normal left ventricle (LV) function, and single-vessel disease of the left anterior descending artery (LAD), the cost-effectiveness ratio for PTCA, directional coronary atherectomy, or coronary stenting that can be expected to provide greater than 90% success rate with less than 3% major acute complication rate is very favorable (less than \$20,000 per QALY) compared to medical therapy. The rating also applies to patients with symptomatic angina or documented ischemia and 2-vessel coronary disease in which percutaneous coronary revascularization can be expected to provide a more than 90% success rate with a less than 3% major acute complication rate. In patients with 3-vessel coronary disease who have comorbidities that increase operative risk for CABG surgery, percutaneous coronary intervention (PCI) that is believed to be safe and feasible is reasonably acceptable (\$20,000-\$60,000 per QALY). In patients in the post-MI setting, a strategy of routine, nonsymptom-driven, coronary angiography and PCI performed for critical (greater than 70% diameter stenosis) culprit coronary lesions amenable to balloon angioplasty or stenting has been proposed to be reasonably cost-effective in many subgroups.

In patients with symptomatic angina or documented ischemia and 3-vessel coronary disease, for which bypass surgery can be expected to provide full revascularization and an acute complication rate of less than 5%, the cost-effectiveness of PCI is not well established. Although PTCA for 2- and 3-vessel coronary disease appears to be as safe, but initially less expensive than CABG surgery, the costs of PTCA converge towards the higher costs of bypass surgery after 3 to 5 years. Thus, whereas PTCA or CABG surgery has been shown to be cost-effective compared with medical therapy, there is no evidence for incremental cost-effectiveness of PTCA over bypass surgery for 2- or 3-vessel coronary disease in patients who are considered good candidates for both procedures. For patients with 1- or 2-vessel coronary disease who are asymptomatic or have only mild angina, without documented left main disease, the estimated cost-effectiveness ratios for PCI are greater than \$80,000 per QALY compared with medical therapy, and are thus considered less favorable.

The initial mean cost of angioplasty was 65% that of surgery, but need for repeat interventions increased medical expenses so that after 5 years the total medical cost of PTCA was 95% that of surgery (\$56,225 vs. \$58,889), a significant difference of \$2,664 ( $p = 0.047$ ). Compared with CABG, PTCA appeared less costly for patients with 2-vessel disease, but not for patients with 3-vessel disease.

The use of drug-eluting stents (DES) is affecting the cost-effectiveness of PCI. In the SIRIUS (Sirolimus-Eluting Balloon Expandable Stent in the Treatment of Patients With De Novo Native Coronary Artery Lesions) trial, there were 21 fewer repeat revascularization procedures per 100 patients treated with the sirolimus stent. Although the DES group's hospital costs were \$2800 more, much of that was negated in follow-up by the high reintervention rate in the bare-metal stent (BMS) group. However, the number of repeat procedures in such trials with routine angiographic follow-up is inflated compared with registries of BMS, which suggests only 6 to 7 repeat procedures are avoided by routinely using DES. The ultimate cost effectiveness of drug-eluting stenting will depend on the cost of the stents, how many are implanted per patient, and how many repeat procedures are avoided.

Because cost-effectiveness analysis research is new in the field of PCI, its results are limited. The Committee underscores the need for cost containment and careful decision making regarding the use of PCI strategies.

## METHOD OF GUIDELINE VALIDATION

External Peer Review  
Internal Peer Review

## DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This document was reviewed by two official reviewers nominated by the American College of Cardiology (ACC), two official reviewers nominated by the American Heart Association (AHA); two official reviewers nominated by the Society for Cardiac Angiography and Interventions (SCAI); one official reviewer from the ACC/AHA Task Force of Practice Guidelines; and eight content reviewers, including members from the AHA Committee on Diagnostic and Interventional Cardiac Catheterization and the American College of Cardiology Foundation (ACCF) Cardiac Catheterization and Intervention Committee.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Definitions for the weight of the evidence (A-C) and classes of recommendations (I-III) are provided at the end of the "Major Recommendations" field.

#### Outcomes

Acute Outcome: Procedural Complications

## Class I

All patients who have signs or symptoms suggestive of myocardial infarction (MI) during or after percutaneous coronary interventions (PCI) and those with complicated procedures should have creatine kinase-MB isoenzyme (CK-MB) and troponin I or T measured after the procedure. (Level of Evidence: B)

## Class IIa

Routine measurement of cardiac biomarkers (CK-MB and/or troponin I or T) in all patients undergoing PCI is reasonable 8 to 12 hours after the procedure. (Level of Evidence: C)

## Institutional and Operator Competency

### Quality Assurance

## Class I

1. An institution that performs PCI should establish an ongoing mechanism for valid peer review of its quality and outcomes. Review should be conducted both at the level of the entire program and at the level of the individual practitioner. Quality-assessment reviews should take risk adjustment, statistical power, and national benchmark statistics into consideration. Quality-assessment reviews should include both tabulation of adverse event rates for comparison with benchmark values and case review of complicated procedures and some uncomplicated procedures. (Level of Evidence: C)
2. An institution that performs PCI should participate in a recognized PCI data registry for the purpose of benchmarking its outcomes against current national norms. (Level of Evidence: C)

### Operator and Institutional Volume

## Class I

1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures) at high-volume centers (more than 400 procedures) with onsite cardiac surgery. (Hirshfeld, Ellis, & Faxon, 1998; Hirshfeld et al., 1999) (Level of Evidence: B)
2. Elective PCI should be performed by operators and institutions whose historical and current risk-adjusted outcomes statistics are comparable to those reported in contemporary national data registries. (Level of Evidence: C)
3. Primary PCI for ST-segment elevation myocardial infarction (STEMI) should be performed by experienced operators who perform more than 75 elective PCI procedures per year and, ideally, at least 11 PCI procedures for STEMI per year. Ideally, these procedures should be performed in institutions that perform more than 400 elective PCIs per year and more than 36 primary PCI procedures for STEMI per year. (Level of Evidence B)

## Class IIa



1. It is reasonable that operators with acceptable volume (at least 75 PCI procedures per year) perform PCI at low-volume centers (200 to 400 PCI procedures per year) with onsite cardiac surgery. (Hirshfeld, Ellis, & Faxon, 1998; Hirshfeld et al., 1999) (Level of Evidence: B)
2. It is reasonable that low-volume operators (fewer than 75 PCI procedures per year) perform PCI at high-volume centers (more than 400 PCI procedures per year) with onsite cardiac surgery. Ideally, operators with an annual procedure volume less than 75 should only work at institutions with an activity level of more than 600 procedures per year. Operators who perform fewer than 75 procedures per year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume of at least 150 procedures per year. (Level of Evidence: B)

#### Class IIb

The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 procedures per year (or fewer than 11 PCIs for STEMI per year) is not well established. (Level of Evidence: C)

#### Class III

It is not recommended that elective PCI be performed by low-volume operators (fewer than 75 procedures per year) at low-volume centers (200 to 400) with or without onsite cardiac surgery. (Hirshfeld, Ellis, & Faxon, 1998; Hirshfeld et al., 1999) An institution with a volume of fewer than 200 procedures per year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer this service. (Level of Evidence: B)

#### Role of Onsite Cardiac Surgical Back-Up

##### Class I

1. Elective PCI should be performed by operators with acceptable annual volume (at least 75 procedures per year) at high-volume centers (more than 400 procedures annually) that provide immediately available onsite emergency cardiac surgical services. (Level of Evidence: B)
2. Primary PCI for patients with STEMI should be performed in facilities with onsite cardiac surgery. (Level of Evidence: B)

##### Class III

Elective PCI should not be performed at institutions that do not provide onsite cardiac surgery. (Level of Evidence: C)\*

\*Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program. A small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer. One study found higher mortality in the Medicare database for

patients undergoing elective PCI in institutions without onsite cardiac surgery. This recommendation may be subject to revision as clinical data and experience increase.

## Primary PCI for STEMI Without Onsite Cardiac Surgery

### Class IIb

Primary PCI for patients with STEMI might be considered in hospitals without onsite cardiac surgery, provided that appropriate planning for program development has been accomplished, including appropriately experienced physician operators (more than 75 total PCIs and, ideally, at least 11 primary PCIs per year for STEMI), an experienced catheterization team on a 24 hours per day, 7 days per week call schedule, and a well-equipped catheterization laboratory with digital imaging equipment, a full array of interventional equipment, and intra-aortic balloon pump capability, and provided that there is a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital with appropriate hemodynamic support capability for transfer. The procedure should be limited to patients with STEMI or MI with new or presumably new left bundle-branch block on electrocardiogram (ECG) and should be performed in a timely fashion (goal of balloon inflation within 90 minutes of presentation) by persons skilled in the procedure (at least 75 PCIs per year) and at hospitals performing a minimum of 36 primary PCI procedures per year. (Level of Evidence: B)

### Class III

Primary PCI should not be performed in hospitals without onsite cardiac surgery and without a proven plan for rapid transport to a cardiac surgery operating room in a nearby hospital or without appropriate hemodynamic support capability for transfer. (Level of Evidence: C)

## Criteria for the Performance of Primary PCI at Hospitals Without On-Site Cardiac Surgery

- The operators must be experienced interventionalists who regularly perform elective PCI at a surgical center (greater than or equal to 75 cases per year). The catheterization laboratory must perform a minimum of 36 primary PCI procedures per year.
- The nursing and technical catheterization laboratory staff must be experienced in handling acutely ill patients and must be comfortable with interventional equipment. They must have acquired experience in dedicated interventional laboratories at a surgical center. They participate in a 24-hours-per-day, 365-days-per-year call schedule.
- The catheterization laboratory itself must be well-equipped, with optimal imaging systems, resuscitative equipment, and intra-aortic balloon pump (IABP) support, and must be well-stocked with a broad array of interventional equipment.
- The cardiac care unit nurses must be adept in hemodynamic monitoring and IABP management.
- The hospital administration must fully support the program and enable the

fulfillment of the above institutional requirements.

- There must be formalized written protocols in place for immediate and efficient transfer of patients to the nearest cardiac surgical facility that are reviewed/tested on a regular (quarterly) basis.
- Primary PCI must be performed routinely as the treatment of choice around the clock for a large proportion of patients with acute myocardial infarction (AMI), to ensure streamlined care paths and increased case volumes.
- Case selection for the performance of primary PCI must be rigorous. Criteria for the types of lesions appropriate for primary PCI and for the selection for transfer for emergency aortocoronary bypass surgery are shown in Table 14 of the original guideline document.
- There must be an ongoing program of outcomes analysis and formalized periodic case review.
- Institutions should participate in a 3- to 6-month period of implementation, during which time development of a formalized primary PCI program is instituted that includes establishment of standards, training of staff, detailed logistic development, and creation of a quality-assessment and error-management system.

#### Patient Selection for Primary PCI and Emergency Aortocoronary Bypass at Hospitals Without On-Site Cardiac Surgery

Avoid intervention in hemodynamically stable patients with:

- Significant (greater than or equal to 60%) stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter
- Extremely long or angulated infarct-related lesions with Thrombolysis In Myocardial Infarction (TIMI) grade 3 flow
- Infarct-related lesions with TIMI grade 3 flow in stable patients with 3-vessel disease
- Infarct-related lesions of small or secondary vessels
- Hemodynamically significant lesions in other than the infarct artery

Transfer for emergency aortocoronary bypass surgery patients with:

- High-grade residual left main or multivessel coronary disease and clinical or hemodynamic instability present after primary PCI of occluded vessels, preferably with IABP support.

#### Elective PCI Without Onsite Surgery

##### Class III

Elective PCI should not be performed at institutions that do not provide onsite cardiac surgery. (Level of Evidence: C)\*

\*Several centers have reported satisfactory results based on careful case selection with well-defined arrangements for immediate transfer to a surgical program. A

small, but real fraction of patients undergoing elective PCI will experience a life-threatening complication that could be managed with the immediate onsite availability of cardiac surgical support but cannot be managed effectively by urgent transfer. One study found higher mortality in the Medicare database for patients undergoing elective PCI in institutions without onsite cardiac surgery. This recommendation may be subject to revision as clinical data and experience increase.

### Clinical Presentations

#### Patients With Asymptomatic Ischemia or Canadian Cardiovascular Society (CCS) Class I or II Angina

##### Class IIa

1. PCI is reasonable in patients with asymptomatic ischemia or CCS class I or II angina and with 1 or more significant lesions in 1 or 2 coronary arteries suitable for PCI with a high likelihood of success and a low risk of morbidity and mortality. The vessels to be dilated must subtend a moderate to large area of viable myocardium or be associated with a moderate to severe degree of ischemia on noninvasive testing. (Level of Evidence: B)
2. PCI is reasonable for patients with asymptomatic ischemia or CCS class I or II angina, and recurrent stenosis after PCI with a large area of viable myocardium or high-risk criteria on noninvasive testing. (Level of Evidence: C)
3. Use of PCI is reasonable in patients with asymptomatic ischemia or CCS class I or II angina with significant left main coronary artery disease (CAD) (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for coronary artery bypass grafting (CABG). (Level of Evidence: B)

##### Class IIb

1. The effectiveness of PCI for patients with asymptomatic ischemia or CCS class I or II angina who have 2- or 3-vessel disease with significant proximal left anterior descending (LAD) artery CAD who are otherwise eligible for CABG with 1 arterial conduit and who have treated diabetes or abnormal LV function is not well established. (Level of Evidence: B)
2. PCI might be considered for patients with asymptomatic ischemia or CCS class I or II angina with nonproximal LAD CAD that subtends a moderate area of viable myocardium and demonstrates ischemia on noninvasive testing. (Level of Evidence: C)

##### Class III

PCI is not recommended in patients with asymptomatic ischemia or CCS class I or II angina who do not meet the criteria as listed under the class II recommendations or who have 1 or more of the following:

- a. Only a small area of viable myocardium at risk (Level of Evidence: C)
- b. No objective evidence of ischemia (Level of Evidence: C)

- c. Lesions that have a low likelihood of successful dilatation (Level of Evidence: C)
- d. Mild symptoms that are unlikely to be due to myocardial ischemia (Level of Evidence: C)
- e. Factors associated with increased risk of morbidity or mortality (Level of Evidence: C)
- f. Left main disease and eligibility for CABG (Level of Evidence: C)
- g. Insignificant disease (less than 50% coronary stenosis) (Level of Evidence: C)

#### Grading of Angina Pectoris According to Canadian Cardiovascular Society (CCS) Classification

Class	Description of Stage
I	"Ordinary physical activity does not cause...angina," such as walking or climbing stairs. Angina occurs with strenuous, rapid, or prolonged exertion at work or recreation.
II	"Slight limitation of ordinary activity." Angina occurs on walking or climbing stairs rapidly; walking uphill; walking or stair climbing after meals; in cold, in wind, or under emotional stress; or only during the few hours after awaking.  Angina occurs on walking more than 2 blocks on the level and climbing more than 1 flight of ordinary stairs at a normal pace and under normal conditions.
III	"Marked limitations of ordinary physical activity." Angina occurs on walking 1 to 2 blocks on the level and climbing 1 flight of stairs under normal conditions and at a normal pace.
IV	"Inability to carry on any physical activity without discomfort--anginal symptoms may be present at rest."

#### Provider Checklist: Key Areas for Consideration

##### Patients at High Risk

- Assess key clinical and anatomic variables.
- Consider alternative therapies such as CABG in consultation with the patient.
- Ensure that formalized surgical standby is available.
- Ensure periprocedural hemodynamic support is available.

##### Patients at Low Risk

- Assess key clinical and anatomic variables.
- Consider alternative therapies such as medical therapy in consultation with the patient.

#### Patients With CCS Class III Angina

##### Class IIa

1. It is reasonable that PCI be performed in patients with CCS class III angina and single-vessel or multivessel CAD who are undergoing medical therapy

- and who have 1 or more significant lesions in 1 or more coronary arteries suitable for PCI with a high likelihood of success and low risk of morbidity or mortality. (Level of Evidence: B)
2. It is reasonable that PCI be performed in patients with CCS class III angina with single-vessel or multivessel CAD who are undergoing medical therapy with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery. (Level of Evidence: C)
  3. Use of PCI is reasonable in patients with CCS class III angina with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG. (Level of Evidence: B)

#### Class IIb

1. PCI may be considered in patients with CCS class III angina with single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more lesions to be dilated with a reduced likelihood of success. (Level of Evidence: B)
2. PCI may be considered in patients with CCS class III angina and no evidence of ischemia on noninvasive testing or who are undergoing medical therapy and have 2- or 3-vessel CAD with significant proximal LAD CAD and treated diabetes or abnormal LV function. (Level of Evidence: B)

#### Class III

PCI is not recommended for patients with CCS class III angina with single-vessel or multivessel CAD, no evidence of myocardial injury or ischemia on objective testing, and no trial of medical therapy, or who have 1 of the following:

- a. Only a small area of myocardium at risk (Level of Evidence: C)
- b. All lesions or the culprit lesion to be dilated with morphology that conveys a low likelihood of success (Level of Evidence: C)
- c. A high risk of procedure-related morbidity or mortality (Level of Evidence: C)
- d. Insignificant disease (less than 50% coronary stenosis) (Level of Evidence: C)
- e. Significant left main CAD and candidacy for CABG (Level of Evidence: C)

#### Patients With Unstable Angina (UA)/Non-ST-Segment Elevation Myocardial Infarction (NSTEMI)

##### Class I

An early invasive PCI strategy is indicated for patients with UA/NSTEMI who have no serious comorbidity and coronary lesions amenable to PCI. Patients must have any of the following high-risk features:

- a. Recurrent ischemia despite intensive anti-ischemic therapy (Level of Evidence: A)
- b. Elevated troponin level (Level of Evidence: A)
- c. New ST-segment depression (Level of Evidence: A)
- d. Heart failure (HF) symptoms or new or worsening mitral regurgitation (MR) (Level of Evidence: A)
- e. Depressed LV systolic function (Level of Evidence: A)

- f. Hemodynamic instability (Level of Evidence: A)
- g. Sustained ventricular tachycardia (Level of Evidence: A)
- h. PCI within 6 months (Level of Evidence: A)
- i. Prior CABG (Level of Evidence: A)

#### Class IIa

- 1. It is reasonable that PCI be performed in patients with UA/NSTEMI and single-vessel or multivessel CAD who are undergoing medical therapy with focal saphenous vein graft lesions or multiple stenoses who are poor candidates for reoperative surgery. (Level of Evidence: C)
- 2. In the absence of high-risk features associated with UA/NSTEMI, it is reasonable to perform PCI in patients with amenable lesions and no contraindication for PCI with either an early invasive or early conservative strategy. (Level of Evidence: B)
- 3. Use of PCI is reasonable in patients with UA/NSTEMI with significant left main CAD (greater than 50% diameter stenosis) who are candidates for revascularization but are not eligible for CABG. (Level of Evidence: B)

#### Class IIb

- 1. In the absence of high-risk features associated with UA/NSTEMI, PCI may be considered in patients with single-vessel or multivessel CAD who are undergoing medical therapy and who have 1 or more lesions to be dilated with reduced likelihood of success. (Level of Evidence: B)
- 2. PCI may be considered in patients with UA/NSTEMI who are undergoing medical therapy who have 2- or 3-vessel disease, significant proximal LAD CAD, and treated diabetes or abnormal left ventricular (LV) function. (Level of Evidence: B)

#### Class III

In the absence of high-risk features associated with UA/NSTEMI, PCI is not recommended for patients with UA/NSTEMI who have single-vessel or multivessel CAD and no trial of medical therapy, or who have 1 or more of the following:

- a. Only a small area of myocardium at risk (Level of Evidence: C)
- b. All lesions or the culprit lesion to be dilated with morphology that conveys a low likelihood of success (Level of Evidence: C)
- c. A high risk of procedure-related morbidity or mortality (Level of Evidence: C)
- d. Insignificant disease (less than 50% coronary stenosis) (Level of Evidence: C)
- e. Significant left main CAD and candidacy for CABG (Level of Evidence: B)

#### Patients With STEMI

#### General and Specific Considerations

#### Class I

#### General Considerations

1. If immediately available, primary PCI should be performed in patients with STEMI (including true posterior MI) or MI with new or presumably new left bundle-branch block who can undergo PCI of the infarct artery within 12 hours of symptom onset, if performed in a timely fashion (balloon inflation goal within 90 minutes of presentation) by persons skilled in the procedure (individuals who perform more than 75 PCI procedures per year, ideally at least 11 PCIs per year for STEMI). The procedure should be supported by experienced personnel in an appropriate laboratory environment (one that performs more than 200 PCI procedures per year, of which at least 36 are primary PCI for STEMI, and that has cardiac surgery capability). (Level of Evidence: A) Primary PCI should be performed as quickly as possible, with a goal of a medical contact-to-balloon or door-to-balloon time within 90 minutes. (Level of Evidence: B)

#### Specific Considerations

2. Primary PCI should be performed for patients less than 75 years old with ST elevation or presumably new left bundle-branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. (Level of Evidence: A)
3. Primary PCI should be performed in patients with severe congestive heart failure and/or pulmonary edema (Killip class 3) and onset of symptoms within 12 hours. The medical contact-to-balloon or door-to balloon time should be as short as possible (i.e., goal within 90 minutes). (Level of Evidence: B)

#### Class IIa

1. Primary PCI is reasonable for selected patients 75 years or older with ST elevation or left bundle-branch block or who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. (Level of Evidence: B)
2. It is reasonable to perform primary PCI for patients with onset of symptoms within the prior 12 to 24 hours and 1 or more of the following:
  - a. Severe congestive heart failure (Level of Evidence: C)
  - b. Hemodynamic or electrical instability (Level of Evidence: C)
  - c. Evidence of persistent ischemia (Level of Evidence: C)

#### Class IIb

The benefit of primary PCI for STEMI patients eligible for fibrinolysis when performed by an operator who performs fewer than 75 PCI procedures per year (or fewer than 11 PCIs for STEMI per year) is not well established. (Level of Evidence: C)

#### Class III



1. Elective PCI should not be performed in a noninfarct-related artery at the time of primary PCI of the infarct related artery in patients without hemodynamic compromise. (Level of Evidence: C)
2. Primary PCI should not be performed in asymptomatic patients more than 12 hours after onset of STEMI who are hemodynamically and electrically stable. (Level of Evidence: C)

#### PCI in Fibrinolytic-Ineligible Patients

##### Class I

Primary PCI should be performed in fibrinolytic-ineligible patients who present with STEMI within 12 hours of symptom onset. (Level of Evidence: C)

##### Class IIa

It is reasonable to perform primary PCI for fibrinolytic-ineligible patients with onset of symptoms within the prior 12 to 24 hours and 1 or more of the following:

- a. Severe congestive heart failure. (Level of Evidence: C)
- b. Hemodynamic or electrical instability. (Level of Evidence: C)
- c. Evidence of persistent ischemia. (Level of Evidence: C)

#### Facilitated PCI

##### Class IIb

Facilitated PCI might be performed as a reperfusion strategy in higher-risk patients when PCI is not immediately available and bleeding risk is low. (Level of Evidence: B)

#### PCI After Failed Fibrinolysis (Rescue PCI)

##### Class I

1. Rescue PCI should be performed in patients less than 75 years old with ST elevation or left bundle-branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. (Level of Evidence: B)
2. Rescue PCI should be performed in patients with severe congestive heart failure and/or pulmonary edema (Killip class 3) and onset of symptoms within 12 hours. (Level of Evidence: B)

##### Class IIa

1. Rescue PCI is reasonable for selected patients 75 years or older with ST elevation or left bundle-branch block or who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for

- revascularization and agree to invasive care may be selected for such an invasive strategy. (Level of Evidence: B)
2. It is reasonable to perform rescue PCI for patients with 1 or more of the following:
    - a. Hemodynamic or electrical instability. (Level of Evidence: C)
    - b. Evidence of persistent ischemia. (Level of Evidence: C)

### Class III

Rescue PCI in the absence of 1 or more of the above class I or IIa indications is not recommended. (Level of Evidence: C)

### PCI After Successful Fibrinolysis or for Patients Not Undergoing Primary Reperfusion

#### Class I

1. In patients whose anatomy is suitable, PCI should be performed when there is objective evidence of recurrent MI. (Level of Evidence: C)
2. In patients whose anatomy is suitable, PCI should be performed for moderate or severe spontaneous or provokable myocardial ischemia during recovery from STEMI. (Level of Evidence: B)
3. In patients whose anatomy is suitable, PCI should be performed for cardiogenic shock or hemodynamic instability. (Level of Evidence: B)

#### Class IIa

1. It is reasonable to perform routine PCI in patients with LV ejection fraction less than or equal to 0.40, HF, or serious ventricular arrhythmias. (Level of Evidence: C)
2. It is reasonable to perform PCI when there is documented clinical heart failure during the acute episode, even though subsequent evaluation shows preserved LV function (LV ejection fraction greater than 0.40). (Level of Evidence: C)

#### Class IIb

PCI might be considered as part of an invasive strategy after fibrinolytic therapy. (Level of Evidence: C)

### PCI for Cardiogenic Shock

#### Class I

Primary PCI is recommended for patients less than 75 years old with ST elevation or left bundle-branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock, unless further support is futile because of the patient's wishes or contraindications/unsuitability for further invasive care. (Level of Evidence: A)

#### Class IIa

Primary PCI is reasonable for selected patients 75 years or older with ST elevation or left bundle-branch block who develop shock within 36 hours of MI and are suitable for revascularization that can be performed within 18 hours of shock. Patients with good prior functional status who are suitable for revascularization and agree to invasive care may be selected for such an invasive strategy. (Level of Evidence: B)

#### Percutaneous Intervention in Patients With Prior Coronary Bypass Surgery

##### Class I

1. When technically feasible, PCI should be performed in patients with early ischemia (usually within 30 days) after CABG. (Level of Evidence: B)
2. It is recommended that distal embolic protection devices be used when technically feasible in patients undergoing PCI to saphenous vein grafts. (Level of Evidence: B)

##### Class IIa

1. PCI is reasonable in patients with ischemia that occurs 1 to 3 years after CABG and who have preserved LV function with discrete lesions in graft conduits. (Level of Evidence: B)
2. PCI is reasonable in patients with disabling angina secondary to new disease in a native coronary circulation after CABG. (If angina is not typical, objective evidence of ischemia should be obtained.) (Level of Evidence: B)
3. PCI is reasonable in patients with diseased vein grafts more than 3 years after CABG. (Level of Evidence: B)
4. PCI is reasonable when technically feasible in patients with a patent left internal mammary artery graft who have clinically significant obstructions in other vessels. (Level of Evidence: C)

##### Class III

1. PCI is not recommended in patients with prior CABG for chronic total vein graft occlusions. (Level of Evidence: B)
2. PCI is not recommended in patients who have multiple target lesions with prior CABG and who have multivessel disease, failure of multiple saphenous vein grafts (SVGs), and impaired LV function unless repeat CABG poses excessive risk due to severe comorbid conditions. (Level of Evidence: B)

#### Use of Adjunctive Technology (Intracoronary Ultrasound Imaging, Flow Velocity, and Pressure)

##### Intravascular Ultrasound Imaging (IVUS)

##### Class IIa

IVUS is reasonable for the following:

- a. Assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent (Level of Evidence: B)
- b. Determination of the mechanism of stent restenosis (inadequate expansion versus neointimal proliferation) and to enable selection of appropriate therapy (vascular brachytherapy versus repeat balloon expansion) (Level of Evidence: B)
- c. Evaluation of coronary obstruction at a location difficult to image by angiography in a patient with a suspected flow-limiting stenosis (Level of Evidence: C)
- d. Assessment of a suboptimal angiographic result after PCI (Level of Evidence: C)
- e. Establishment of the presence and distribution of coronary calcium in patients for whom adjunctive rotational atherectomy is contemplated (Level of Evidence: C)
- f. Determination of plaque location and circumferential distribution for guidance of directional coronary atherectomy (Level of Evidence: B)

#### Class IIb

Intravascular ultrasound (IVUS) may be considered for the following:

- a. Determination of the extent of atherosclerosis in patients with characteristic anginal symptoms and a positive functional study with no focal stenoses or mild CAD on angiography (Level of Evidence: C)
- b. Preinterventional assessment of lesional characteristics and vessel dimensions as a means to select an optimal revascularization device (Level of Evidence: C)
- c. Diagnosis of coronary disease after cardiac transplantation (Level of Evidence: C)

#### Class III

IVUS is not recommended when the angiographic diagnosis is clear and no interventional treatment is planned. (Level of Evidence: C)

Coronary Artery Pressure and Flow: Use of Fractional Flow Reserve and Coronary Vasodilatory Reserve

#### Class IIa

It is reasonable to use intracoronary physiologic measurements (Doppler ultrasound, fractional flow reserve) in the assessment of the effects of intermediate coronary stenoses (30% to 70% luminal narrowing) in patients with anginal symptoms. Coronary pressure or Doppler velocimetry may also be useful as an alternative to performing noninvasive functional testing (e.g., when the functional study is absent or ambiguous) to determine whether an intervention is warranted. (Level of Evidence: B)

#### Class IIb

1. Intracoronary physiologic measurements may be considered for the evaluation of the success of PCI in restoring flow reserve and to predict the risk of restenosis. (Level of Evidence: C)
2. Intracoronary physiologic measurements may be considered for the evaluation of patients with anginal symptoms without an apparent angiographic culprit lesion. (Level of Evidence: C)

### Class III

Routine assessment with intracoronary physiologic measurements such as Doppler ultrasound or fractional flow reserve to assess the severity of angiographic disease in patients with a positive, unequivocal noninvasive functional study is not recommended. (Level of Evidence: C)

## Management of Patients Undergoing PCI

### Evolution Technologies

#### Acute Results

### Class I

It is recommended that distal embolic protection devices be used when technically feasible in patients undergoing PCI to saphenous vein grafts. (Level of Evidence: B)

### Antiplatelet and Antithrombotic Adjunctive Therapies for PCI

#### Oral Antiplatelet Therapy

### Class I

1. Patients already taking daily chronic aspirin therapy should take 75 to 325 mg of aspirin before the PCI procedure is performed. (Level of Evidence: A)
2. Patients not already taking daily chronic aspirin therapy should be given 300 to 325 mg of aspirin for at least 2 hours and preferably 24 hours before the PCI procedure is performed. (Level of Evidence: C)
3. After the PCI procedure, in patients with neither aspirin resistance, allergy, nor increased risk of bleeding, aspirin 325 mg daily should be given for at least 1 month after bare-metal stent implantation, 3 months after sirolimus-eluting stent implantation, and 6 months after paclitaxel-eluting stent implantation, after which daily chronic aspirin use should be continued indefinitely at a dose of 75 to 162 mg. (Level of Evidence: B)
4. A loading dose of clopidogrel should be administered before PCI is performed. (Level of Evidence: A) An oral loading dose of 300 mg, administered at least 6 hours before the procedure, has the best established evidence of efficacy. (Level of Evidence: B)
5. In patients who have undergone PCI, clopidogrel 75 mg daily should be given for at least 1 month after bare-metal stent implantation (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 weeks), 3 months after sirolimus stent implantation, and 6 months after

paclitaxel stent implantation, and ideally up to 12 months in patients who are not at high risk of bleeding. (Level of Evidence: B)

#### Class IIa

1. If clopidogrel is given at the time of procedure, supplementation with glycoprotein (GP) IIb/IIIa receptor antagonists can be beneficial to facilitate earlier platelet inhibition than with clopidogrel alone. (Level of Evidence: B)
2. For patients with an absolute contraindication to aspirin, it is reasonable to give a 300-mg loading dose of clopidogrel, administered at least 6 hours before PCI, and/or GP IIb/IIIa antagonists, administered at the time of PCI. (Level of Evidence: C)
3. When a loading dose of clopidogrel is administered, a regimen of greater than 300 mg is reasonable to achieve higher levels of antiplatelet activity more rapidly, but the efficacy and safety compared with a 300-mg loading dose are less established. (Level of Evidence: C)
4. It is reasonable that patients undergoing brachytherapy be given daily clopidogrel 75 mg indefinitely and daily aspirin 75 to 325 mg indefinitely unless there is significant risk for bleeding. (Level of Evidence: C)

#### Class IIb

In patients in whom subacute thrombosis may be catastrophic or lethal (unprotected left main, bifurcating left main, or last patent coronary vessel), platelet aggregation studies may be considered and the dose of clopidogrel increased to 150 mg per day if less than 50% inhibition of platelet aggregation is demonstrated. (Level of Evidence: C)

#### Glycoprotein IIb/IIIa Inhibitors

##### Class I

In patients with UA/NSTEMI undergoing PCI without clopidogrel administration, a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban) should be administered. (Level of Evidence: A)\*

##### Class IIa

1. In patients with UA/NSTEMI undergoing PCI with clopidogrel administration, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban). (Level of Evidence: B)\*
2. In patients with STEMI undergoing PCI, it is reasonable to administer abciximab as early as possible. (Level of Evidence: B)
3. In patients undergoing elective PCI with stent placement, it is reasonable to administer a GP IIb/IIIa inhibitor (abciximab, eptifibatide, or tirofiban). (Level of Evidence: B)

##### Class IIb

In patients with STEMI undergoing PCI, treatment with eptifibatide or tirofiban may be considered. (Level of Evidence: C)

\*It is acceptable to administer the GP IIb/IIIa inhibitor before performance of the diagnostic angiogram ("upstream treatment") or just before PCI ("in-lab treatment").

#### Recommendations for Use of GP IIb/IIIa Inhibitors in Patients Undergoing PCI

UA/NSTEMI and Clopidogrel Used	UA/NSTEMI and Clopidogrel Not Used	STEMI	Elective PCI
Abciximab, eptifibatide, or tirofiban  Class IIa; LOE: B	Abciximab, eptifibatide, or tirofiban  Class I; LOE: A	Abciximab  Class IIa; LOE: B  Eptifibatide or tirofiban  Class IIb; LOE: C	Abciximab, eptifibatide, or tirofiban  Class IIa; LOE: B

LOE indicates level of evidence

#### Antithrombotic Therapy

##### Unfractionated Heparin, Low-Molecular-Weight Heparin, and Bivalirudin

#### Class I

1. Unfractionated heparin should be administered to patients undergoing PCI. (Level of Evidence: C)
2. For patients with heparin-induced thrombocytopenia, it is recommended that bivalirudin or argatroban be used to replace heparin. (Level of Evidence: B)

#### Class IIa

1. It is reasonable to use bivalirudin as an alternative to unfractionated heparin and glycoprotein IIb/IIIa antagonists in low-risk patients undergoing elective PCI. (Level of Evidence: B)
2. Low-molecular-weight heparin is a reasonable alternative to unfractionated heparin in patients with UA/NSTEMI undergoing PCI. (Level of Evidence: B)

#### Class IIb

Low-molecular-weight heparin may be considered as an alternative to unfractionated heparin in patients with STEMI undergoing PCI. (Level of Evidence: B)

#### Post-PCI Management

##### Left Main CAD

## Class IIa

It is reasonable that patients undergoing PCI to unprotected left main coronary obstructions be followed up with coronary angiography between 2 and 6 months after PCI. (Level of Evidence: C)

### Comprehensive Risk Reduction for Patients With Coronary and Other Vascular Disease After PCI

Goals	Intervention Recommendations
Smoking:  <u>Goal</u> Complete cessation. No exposure to environmental tobacco smoke	Ask about tobacco status at every visit. Strongly encourage patient and family to stop smoking and to avoid environmental tobacco smoke. Assess the tobacco user's willingness to quit. Assist by counseling and developing a plan for quitting. Arrange follow-up, referral to special programs, or pharmacological therapy (including nicotine replacement and bupropion). Urge avoidance of exposure to environmental tobacco smoke at work and home.
Blood pressure control:  <u>Goal</u> Less than 140 over 90 mm Hg or less than 130 over 80 mm Hg if chronic kidney disease or diabetes is present	If blood pressure is 120 over 80 mm Hg or greater: <ul style="list-style-type: none"><li>• Initiate or maintain lifestyle modification (weight control, increased physical activity, alcohol moderation, moderate sodium restriction, and emphasis on fruits, vegetables, and low-fat dairy products) in all patients.</li></ul> If blood pressure is 140 over 90 mm Hg or greater (or 130 over 80 mm Hg or greater for individuals with chronic kidney disease or diabetes): <ul style="list-style-type: none"><li>• Add blood pressure medication, emphasizing the use of beta-blockers and inhibitors of the renin-angiotensin-aldosterone system.</li></ul>
Lipid management:  (Triglyceride [TG] less than 200 mg per dL)  <u>Primary goal</u> Low-density lipoprotein cholesterol (LDL-C) substantially less than 100	Start dietary therapy in all patients (less than 7% of total calories as saturated fat and less than 200 mg of cholesterol per day). Promote physical activity and weight management. Encourage increased consumption of omega-3 fatty acids in fish <sup>7</sup> or 1 g per day omega-3 fatty acids from supplements for risk reduction (for treatment of elevated TG, higher doses are usually necessary for risk reduction).



Goals	Intervention Recommendations
<p>mg per dL (optional target less than 70 mg per dL for very-high-risk patients)<sup>6</sup></p> <p>Lipid management:</p> <p>(TG 200 mg per dL or greater)</p> <p><u>Primary goal</u> Non-high-density lipoprotein cholesterol (HDL-C<sup>1</sup>) substantially less than 130 mg per dL</p>	<p>Assess fasting lipid profile in all patients, preferably within 24 hours of an acute event. For patients hospitalized, initiate lipid-lowering medication as recommended below before discharge according to the following guide:</p> <p>LDL-C less than 100 mg per dL (baseline or on-treatment):</p> <ul style="list-style-type: none"> <li>Statins preferred to lower LDL-C.</li> </ul> <p>LDL-C greater than or equal to 100 mg per dL (baseline or on treatment):</p> <ul style="list-style-type: none"> <li>Initiate or intensify LDL-C-lowering therapy with drug treatment. May require combination therapy with standard-dose ezetimibe, bile acid sequestrant, or niacin.<sup>3</sup></li> </ul> <p>If TG is greater than or equal to 150 mg per dL or HDL-C is less than 40 mg per dL:</p> <ul style="list-style-type: none"> <li>Emphasize weight management and physical activity. Advise smoking cessation.</li> </ul> <p>If TG is 200 to 499 mg per dL:</p> <ul style="list-style-type: none"> <li>After LDL-C-lowering therapy<sup>2,8</sup>, consider adding fibrate or niacin.<sup>3</sup></li> </ul> <p>If TG is greater than or equal to 500 mg per dL:</p> <ul style="list-style-type: none"> <li>Consider fibrate or niacin<sup>3</sup> before LDL-C-lowering therapy.<sup>2,8</sup></li> <li>Consider omega-3 fatty acids as adjunct for high TG.</li> </ul>
<p>Physical activity:</p> <p><u>Minimum goal</u> 30 minutes 5 days per week; optimal daily</p>	<p>Assess risk, preferably with exercise test, to guide prescription. Encourage minimum of 30 to 60 minutes of activity, preferably daily or at least 5 times weekly (brisk walking, jogging, cycling, or other aerobic activity) supplemented by an increase in daily lifestyle activities (e.g., walking breaks at work, gardening, household work). Encourage resistance training 2 days per week.</p>

Goals	Intervention Recommendations
	Cardiac rehabilitation programs are recommended, particularly for those patients with multiple modifiable risk factors and/or those moderate- to high-risk patients in whom supervised exercise training is warranted.
<p>Weight management:</p> <p><u>Goal</u> Body mass index (BMI) 18.5 to 24.9 kg per m<sup>2</sup></p> <p>Waist circumference: Women: Less than 35 inches Men: Less than 40 inches</p>	<p>Calculate BMI and measure waist circumference as part of evaluation. Monitor response of BMI and waist circumference to therapy.</p> <p>Start weight management and physical activity as appropriate. Desirable BMI range: 18.5 to 24.9 kg per m<sup>2</sup>.</p> <p>If waist circumference is 35 inches or greater in women or 40 inches or greater in men, initiate lifestyle changes and consider treatment strategies for metabolic syndrome.</p>
<p>Diabetes management:</p> <p><u>Goal</u> HbA1c less than 7%</p>	<p>Appropriate glucose-lowering therapy to achieve near-normal fasting plasma glucose as indicated by HbA1c.</p> <p>Treatment of other risk factors (e.g., physical activity, weight management, blood pressure cholesterol management).</p>
<p>Antiplatelet agents/anticoagulants:</p>	<p>For all post-PCI stented patients, aspirin 325 mg daily should be given for at least 1 month after bare metal stent implantation, 3 months after sirolimus stent, and 6 months after paclitaxel stent, after which daily chronic aspirin<sup>9</sup> (75 to 162 mg per day) should be continued indefinitely in all patients if not contraindicated.</p> <p>For post-PCI stented patients, clopidogrel 75 mg per day should be given for at least 1 month after bare metal stent implantation, 3 months after sirolimus stent, and 6 months after paclitaxel stent, after which clopidogrel should ideally be continued up to 12 months in all stented patients who are not at high risk of bleeding. Use warfarin in combination with clopidogrel and low-dose aspirin with great caution and when international normalized ratio (INR) is carefully regulated (2.0 to 3.0).</p> <p>Manage warfarin to INR 2.5 to 3.5 for post-MI patients when clinically indicated or for those not able to take aspirin or clopidogrel.</p>

Goals	Intervention Recommendations
Renin-angiotensin- aldosterone system blockers:	<p>Consider angiotensin-converting enzyme (ACE) inhibitors for all CHD patients indefinitely; start early after MI in stable high-risk patients (anterior MI, previous MI, Killip class greater than or equal to II [S3 gallop, rales, radiographic HF]).</p> <p>Continue indefinitely in for all patients with LV dysfunction (ejection fraction less than or equal to 0.40) or symptoms of heart failure.</p> <p>Use as needed to manage blood pressure or consider for chronic therapy in all other patients.</p> <p>Use angiotensin receptor blockers in post-STEMI patients who are intolerant of ACE inhibitors and who have either clinical or radiological signs of heart failure or LVEF less than 0.40.</p> <p>Aldosterone blockade in post-STEMI patients without significant renal dysfunction<sup>4</sup> or hyperkalemia<sup>5</sup> who are already receiving therapeutic doses of an ACE inhibitor, have an LVEF less than or equal to 0.40, and have either diabetes or heart failure.</p>
Beta-blockers:	<p>Start in all post-MI and acute patients (arrhythmia, LV dysfunction, inducible ischemia). Continue for a minimum of 6 months; continue indefinitely in patients with STEMI. Observe usual contraindications. Use as needed to manage angina, rhythm, or blood pressure in all other patients.</p>

<sup>1</sup>Non-HDL-C equals total cholesterol minus HDL cholesterol.

<sup>2</sup>Treat to a goal of non-HDL-C substantially less than 130 mg per dL.

<sup>3</sup>Dietary supplement niacin must not be used as a substitute for prescription niacin.

<sup>4</sup>Creatinine should be less than or equal to 2.5 mg per dL in men and less than or equal to 2.0 mg per dL in women.

<sup>5</sup>Potassium should be less than or equal to 5.0 mEq per liter.

<sup>6</sup>Patients with acute coronary syndromes and other very-high-risk patients (e.g., established CHD plus multiple major risk factors [especially diabetes] or severe and poorly controlled risk factors [especially continued cigarette smoking and/or metabolic syndrome]) should be considered for optional LDL-C goal less than 70 mg per dL.

<sup>7</sup>Pregnant and lactating women should limit their intake of fish to minimize exposure to methylmercury.

<sup>8</sup>The use of resin is relatively contraindicated when TGs are greater than 200 mg per dL.

<sup>9</sup>Some recommend avoiding regular use of ibuprofen, which may limit the cardioprotective effects of aspirin. Use of cyclo-oxygenase-2 inhibitors may be associated with increased incidence of cardiovascular events.

## Special Considerations

### Clinical Restenosis: Background and Management

#### Management Strategies for Restenosis After PTCA

##### Class IIa

It is reasonable to consider that patients who develop restenosis after PTCA or PTCA with atheroablative devices are candidates for repeat coronary intervention with intracoronary stents if anatomic factors are appropriate. (Level of Evidence: B)

#### Drug-Eluting Stents

##### Class I

A drug-eluting stent (DES) should be considered as an alternative to the bare-metal stent in subsets of patients in whom trial data suggest efficacy. (Level of Evidence: A)

##### Class IIb

A DES may be considered for use in anatomic settings in which the usefulness, effectiveness, and safety have not been fully documented in published trials. (Level of Evidence: C)

#### Management Strategies for In-Stent Restenosis (ISR)

### Drug-Eluting Stents (DES)

##### Class IIa

It is reasonable to perform repeat PCI for ISR with a DES or a new DES for patients who develop ISR if anatomic factors are appropriate. (Level of Evidence: B)

## Radiation

##### Class IIa

Brachytherapy can be useful as a safe and effective treatment for ISR. (Level of Evidence: A)

## Exclusion Criteria for Invasive Cardiac Procedures in Settings Without Full-Support Services

Location	Type of Patient	Diagnostic Procedures	Therapeutic Procedures
Hospitals	Adult	<p>Age greater than 75 years NYHA class III or IV heart failure</p> <p>Acute, intermediate, or high-risk ischemic syndromes</p> <p>Recent MI with postinfarction ischemia</p> <p>Pulmonary edema thought to be caused by ischemia</p> <p>Markedly abnormal noninvasive test indicating a high likelihood of left main or severe multivessel coronary disease</p> <p>Known left main coronary artery disease</p> <p>Severe valvular dysfunction, especially in the setting of depressed LV performance</p>	<p>All valvuloplasty procedures, complex adult congenital heart disease diagnostic or therapeutic procedures</p> <p>Diagnostic pericardiocentesis when the effusion is small or moderate in size and there is no tamponade</p> <p>Elective coronary intervention</p>
	Pediatric	No procedures approved	No procedures approved
Freestanding laboratories	Adult	All of the above plus high-risk patients by virtue of comorbid conditions, including need for anticoagulation, poorly controlled hypertension or diabetes, contrast allergy, or renal insufficiency	
	Pediatric	No procedures approved	No procedures approved

### Definitions:

#### Strength of Recommendation

Class I: Conditions for which there is evidence for and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

- Class II a: Weight of evidence/opinion is in favor of usefulness/efficacy.
- Class II b: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective, and in some cases may be harmful.

#### Levels of Evidence

Level of Evidence A: Data derived from multiple randomized clinical trials or meta-analyses.

Level of Evidence B: Data derived from a single randomized trial or nonrandomized studies.

Level of Evidence C: Only consensus opinion of experts, case studies, or standard-of-care.

#### CLINICAL ALGORITHM(S)

None provided

### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

### BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

Appropriate use of percutaneous coronary interventions in the treatment of patients with coronary artery disease

#### POTENTIAL HARMS

- Potential procedural complications of percutaneous coronary interventions (PCI) have been categorized as major (death, myocardial infarction [MI], and stroke) or minor (transient ischemic attack, access site complications, renal insufficiency, or adverse reactions to radiographic contrast). Additional specific complications include intracoronary thrombosis, coronary perforation, tamponade, and arrhythmias.
- Compared with bypass surgery, the disadvantages of percutaneous coronary intervention are early restenosis and the inability to relieve many totally occluded arteries and/or those vessels with extensive atherosclerotic disease.

## Subgroups Most Likely to be Harmed

Coexistent clinical conditions can increase the complication rates for any given anatomic risk factor. For example, complications occurred in 15.4% of patients with diabetes versus 5.8% of patients without diabetes undergoing balloon angioplasty in a multicenter experience. Several studies have reported specific factors associated with increased risk of adverse outcome after percutaneous transluminal coronary angioplasty (PTCA). These factors include advanced age, female gender, unstable angina (UA), congestive heart failure (HF), diabetes, and multivessel coronary artery disease (CAD). Elevated baseline C-reactive protein (CRP) has recently also been shown to be predictive of 30-day death and MI. Other markers of inflammation, such as interleukin-6 and other cytokines, have also been shown to be predictive of outcome.

## CONTRAINDICATIONS

### CONTRAINDICATIONS

#### Contraindications and Cautions for Fibrinolysis in ST-Elevation Myocardial Infarction (STEMI)\*

##### Absolute Contraindications

- Any prior intracranial hemorrhage
- Known structural cerebral vascular lesion (e.g., indicates arteriovenous malformation [AVM])
- Known malignant intracranial neoplasm (primary or metastatic)
- Ischemic stroke within 3 months, EXCEPT acute ischemic stroke within 3 hours
- Suspected aortic dissection
- Active bleeding or bleeding diathesis (excluding menses)
- Significant closed head or facial trauma within 3 months

##### Relative Contraindications

- History of chronic severe, poorly controlled hypertension
- Severe uncontrolled hypertension on presentation (systolic blood pressure (SBP) greater than 180 mm Hg or diastolic blood pressure (DBP) greater than 110 mm Hg)\*\*
- History of prior ischemic stroke greater than 3 months, dementia, or known intracranial pathology not covered in contraindications
- Traumatic or prolonged (greater than 10 minutes) cardiopulmonary resuscitation (CPR) or major surgery (less than 3 weeks)
- Recent (within 2 to 4 weeks) internal bleeding
- Noncompressible vascular punctures
- For streptokinase/anistreplase: prior exposure (more than 5 days ago) or prior allergic reaction to these agents
- Pregnancy
- Active peptic ulcer
- Current use of anticoagulants: the higher the INR, the higher the risk of bleeding

\*Viewed as advisory for clinical decision making and may not be all inclusive or definitive.

\*\*Could be an absolute contraindication in low-risk patients with STEMI

## QUALIFYING STATEMENTS

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- These practice guidelines are intended to assist healthcare providers in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. The guidelines attempt to define practices that meet the needs of most patients in most circumstances. These guideline recommendations reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. If these guidelines are used as the basis for regulatory/payer decisions, the ultimate goal is quality of care and serving the patient's best interests. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all of the circumstances presented by that patient.
- Percutaneous coronary intervention (PCI) is a technique that has been continually refined and modified; hence, continued periodic guideline revision is anticipated. These guidelines are to be viewed as broad recommendations to aid in the appropriate application of PCI. Under unique circumstances, exceptions may exist. These guidelines are intended to complement, not replace, sound medical judgment and knowledge. They are intended for operators who possess the cognitive and technical skills for performing PCI and assume that facilities and resources required to properly perform PCI are available.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

## INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

### IOM CARE NEED

Living with Illness



## IOM DOMAIN

Effectiveness  
Timeliness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Smith SC Jr, Feldman TE, Hirshfeld JW Jr, Jacobs AK, Kern MJ, King SB III, Morrison DA, O'Neill WW, Schaff HV, Whitlow PL, Williams DO. ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention: a report of the American College of Cardiology/American Heart Assoc Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to update the 2001 guidelines for PCI). Bethesda (MD): American College of Cardiology Foundation (ACCF); 2005. 122 p. [926 references]

### ADAPTATION

Not applicable: The guideline was not adapted from another source.

### DATE RELEASED

2001 Jun (revised 2005)

### GUIDELINE DEVELOPER(S)

American College of Cardiology Foundation - Medical Specialty Society  
American Heart Association - Professional Association  
Society for Cardiovascular Angiography and Interventions - Medical Specialty Society

### SOURCE(S) OF FUNDING

The American College of Cardiology Foundation and the American Heart Association. No outside funding is accepted.

### GUIDELINE COMMITTEE

ACC/AHA/SCAI Writing Committee to Update the 2001 Guidelines for Percutaneous Coronary Intervention

American College of Cardiology/American Heart Association Task Force on Practice Guidelines

### COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Writing Committee Members: Sidney C. Smith, Jr, MD, FACC, FAHA, Chair; Ted E. Feldman, MD, FACC, FSCAI\*; John W. Hirshfeld, Jr, MD, FACC, FSCAI\*; Alice K. Jacobs, MD, FACC, FAHA, FSCAI; Morton J. Kern, MD, FACC, FAHA, FSCAI\*;

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\*Society for Cardiovascular Angiography and Interventions (SCAI) Official Representative

\*\*Former Task Force Member during this writing effort

#### FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines makes every effort to avoid any actual, potential, or perceived conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at the first meeting, and updated and reviewed by the writing committee as changes occur.

Table: ACC/AHA/SCAI Committee to Update 2002 Guidelines for Percutaneous Coronary Intervention--Relationships with Industry

Committee Member	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Consultant
Dr. Ted E. Feldman	Abbot; Boston Scientific; Cardia; EV3; Evalve; Guidant	Boston Scientific	None	None
Dr. John W. Hirshfeld, Jr	None	None	None	None
Dr. Alice K. Jacobs	None	None	None	Wyeth
Dr. Morton J. Kern	None	None	None	None
Dr. Spencer B. King, III	Guidant	BMS-Sanofi; Guidant	None	Medtronic; Novoste
Dr. Douglass A. Morrison	None	None	None	None
Dr. William	None	None	None	None

Committee Member	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Consultant
W. O'Neill				
Dr. Hartzell V. Schaff	None	None	None	None
Dr. Sidney C. Smith, Jr	Merck	Bayer	Johnson & Johnson; Medtronic	Bristol-Myers; Squibb; Eli Lilly; Pfizer; Sanofi-Aventis
Dr. Patrick L. Whitlow	Abbot; Cordis, Inc; Fox Hollow Technologies; Lumend, Inc	None	Medtronic	None
Dr. David O. Williams	None	None	None	None

Note: This table represents the relevant relationships of authors with industry that were reported orally at the initial writing committee meeting in July 2002 and updated in conjunction with all meetings and conference calls of the writing committee. It does not reflect any actual or potential relationships at the time of publication.

Table: External Peer Reviewers for the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention\*

Peer Reviewer Name**	Representation	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Consultant/Advisory Board
Dr. Michael Cowley	Official Reviewer -- SCAI	None	None	None	None
Dr. David Faxon	Official Reviewer -- ACC/AHA Task Force on Practice Guidelines	None	None	None	None
Dr. Roxana Mehran	Official Reviewer -- SCAI	None	The Medicines Co.	None	None
Dr. E. Magnus Ohman	Official Reviewer -- AHA	Berlex; Bristol-Myers Squibb; Millennium; Schering-Plough	None	Inovise Medical; Medtronic; Response Medical	None
Dr. Richard Pomerantz	Official Reviewer -- ACCF Board of Governors	None	Aventis	Amgen; Johnson & Johnson; Pfizer; Schering-Plough	Medacorp
Dr. Robert D. Safian	Official Reviewer -- AHA	None	None	None	None

Peer Reviewer Name**	Representation	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Consultant/Advisory Board
Dr. W. Douglas Weaver	Official Reviewer -- ACCF Board of Trustees	None	None	None	None
Dr. Jeffrey L. Anderson	Content Reviewer -- Individual Review	Sanofi/Bristol-Myers Squibb; Novartis	Merck; Sanofi/Bristol-Myers Squibb	None	Merck
Dr. Elliott M. Antman	Content Reviewer -- Individual Review	Aventis; Bayer; Biosite; Boehringer-Mannheim; Bristol-Myers Squibb; British Biotech; Centor; Cor/Millennium; Corvas; Dade; Genentech; Lilly; Merck; Pfizer; Sunol	None	None	Aventis
Dr. Larry S. Dean	Content Reviewer; ACCF Cardiac Catheterization and Intervention Committee	None	None	None	None
Dr. Tommaso Gori	Content Reviewer; AHA Diagnostic and Interventional Cardiac Catheterization Committee	None	None	None	None
Dr. Sharon A. Hunt	Content Reviewer -- Individual Review	None	None	None	None
Dr. Lloyd Klein	Content Reviewer; AHA Diagnostic and Interventional Cardiac Catheterization Committee	None	None	None	None
Dr. Glenn Levine	Content Reviewer; AHA Diagnostic and Interventional Cardiac	None	Aventis	None	None

Peer Reviewer Name**	Representation	Research Grant	Speakers Bureau/Honoraria	Stock Ownership	Consultant/Advisory Board
	Catheterization Committee				
Dr. Joseph P. Ornato	Content Reviewer -- Individual Review	Genentech	None	None	Bristol-Myers Squibb; Genentech

Note: This table represents the relevant relationships of peer reviewers with industry to this topic that were disclosed at the time of peer review of this guideline. It does not necessarily reflect relationships with industry at the time of publication.

\*Participation in the peer review process does not imply endorsement of the document.

\*\*Names are listed in alphabetical order within each category of review.

## GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Smith SC, Dove JT, Jacobs AK, et al. ACC/AHA guidelines for percutaneous coronary intervention (revision of the 1993 PTCA guidelines). J Am Coll Cardiol 2001 Jun; 37(8):2239i-ixvi.

## GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [American College of Cardiology \(ACC\) Web site](#).

Electronic copies also available from the: [American Heart Association \(AHA\) Web site](#) and the [Society for Cardiovascular Angiography and Interventions \(SCAI\) Web site](#).

Print copies: Available from the American College of Cardiology, 9111 Old Georgetown Road, Bethesda, Maryland 20814-1699.

## AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- ACC/AHA/SCAI 2005 guideline update for percutaneous coronary intervention -- summary article. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/SCAI Writing Committee to update the 2001 guidelines for percutaneous coronary intervention). J Am Coll Cardiol 2006; 47:216-35. Available from the [American College of Cardiology \(ACC\) Web site](#).

Also available in Circulation 2006 Feb; 113:e166-e286 and Catheter Cardiovasc Interv 2006 Jan; 67(1):87-112.

- ACC/AHA pocket guideline. Based on the ACC/AHA/SCAI 2005 guideline update. Percutaneous coronary intervention. 2005 Nov. 59 p. Available from the [American College of Cardiology \(ACC\) Web site](#).

Print copies: Available from the American College of Cardiology, 9111 Old Georgetown Road, Bethesda, Maryland 20814-1699.

## PATIENT RESOURCES

None available

## NGC STATUS

This summary was completed by ECRI on October 17, 2001. The information was verified by the guideline developer on January 18, 2002. This summary was updated by ECRI on January 13, 2006. The updated information was verified by the guideline developer on March 22, 2006.

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